



PATENT

Attorney Docket No. 12636-891

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application)	<u>PATENT APPLICATION</u>
)	
Inventor(s): Jorge F. DiMartino)	
)	Art Unit: 1653
Application No.: 09/841,744)	
)	Examiner: KAM, Chih-Min, Ph.D.
Filed: April 24, 2001)	
)	
Title Compositions And Methods For)	
Reestablishing Gene Transcription Through)	
Inhibition of DNA Methylation And Histone)	
<u>Deacetylase</u>)	

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy of each listed publication and U.S. and foreign patent, except for pending U.S. applications, is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

- ☒ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):
- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)
-- OR --
 - ☐ (2) It is being filed within 3 months of entry of a national stage
-- OR --
 - ☐ (3) It is being filed before the mail date of the first Office Action on the merits
-- OR --
 - ☒ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- ☐ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- ☐ a certification as specified in §1.97(e) is provided below; **or**
 - ☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
 - B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
 - C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No. _____), copies are not enclosed herewith.
 - ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

- ☐ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).
- ☐ There are no listed references which are not in the English language.
- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.
- ☐ Attached are the following non-published pending patent applications that may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0 charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.12636-891).

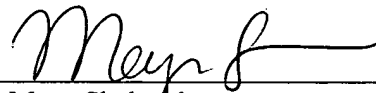
Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: _____

2/25/04

By: _____



Maya Skubatch
Reg. No. 52,505

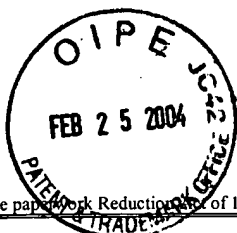
650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971



Under the Paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

PTO/SB/08A (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. Department of Commerce

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application No.	09/841,744
				Filing Date	April 24, 2001
				First Named Inventor	Jorge F. DiMartino
				Art Unit	1653
				Examiner Name	Chih-Min Kam
Sheet	1	Of	2	Attorney Docket No.	12636-891
OTHER PRIOR ART – NON PATENT RELATED DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published			T ²
		BAYLIN, S.B., et al., "Alterations in DNA Methylation: A Fundamental Aspect of Neoplasia," <i>Cancer Res.</i> , (1998) 72:141-196.			
		DASKALAKIS, M., et al., "Expression of a Hypermethylated and Silenced P15/INK4B Gene in a Subgroup of MDS Patients is Restored by Treatment With The Methylation Inhibitor 5-AZA-2'-Deoxycytidine," <i>Abstracts Leukemia Research</i> (2001) Suppl. No. 1, S16-S17.			
		ESTELLER, M., "A Gene Hypermethylation Profile of Human Cancer," <i>Cancer Research</i> (2001) 61:3225-3229.			
		ESTELLER, M., "CpG Island Hypermethylation and Tumor Suppressor Genes: a Booming Present, a Brighter Future," <i>Oncogene</i> (2002) 21:5427-5440.			
		ESTELLER, M., "Epigenetic Lesions Causing Genetic Lesions in Human Cancer: Promoter Hypermethylation of DNA Repair Genes," <i>European Journal of Cancer</i> (2000) 36:2294-2300.			
		GAGNON, J., et al., "Interaction of 5-aza-2'-deoxycytidine and Depsipeptide on Antineoplastic Activity and Activation of 14-3-3σ, E-Cadherin And Tissue Inhibitor of Metalloproteinase 3 Expression in Human Breast Carcinoma Cells," <i>Anti-Cancer Drugs</i> , (2003), 14(3):193-202.			
		JONES, P.A., "DNA Methylation And Cancer," <i>Oncogene</i> , (2002) 21:5358-5360.			
		JONES, P.A., et al., "The Fundamental Role of Epigenetic Events in Cancer," <i>Nature Reviews/Genetics</i> , (2002) 3:415-428.			
		JONES, P.A., et al., "The Role of DNA Methylation in Cancer," <i>Adv. Cancer Res.</i> , (1990) 54:1-23.			
		KARPF, A.R., et al., "Reactivating The Expression of Methylation Silenced Genes in Human Cancer," <i>Oncogene</i> , (2002) 21:5496-5503.			
		LA ROSEE, P., et al., "In Vitro Efficacy of Combined Treatment Depends on the Underlying Mechanism of Resistance in Imatinib-Resistant Bcr-Abl positive Cell Lines," <i>Blood First Edition Paper</i> , prepublished online (2003) DOI 10.1182/blood-2003-04-1074, pp. 1-39.			
		NEPHEW, K.P., et al., "Epigenetic Gene Silencing in Cancer Initiation And Progression," <i>Cancer Letters</i> 190, (2003) pp. 125-133.			
		PAZ, M.F., et al., "A Systematic Profile of DNA Methylation in Human Cancer Cell Lines," <i>Cancer Research</i> 63, (2003) 1114-1121.			
		PRIMEAU, M., et al., "Synergistic Antineoplastic Action of DNA Methylation Inhibitor 5-AZA-2'-Deoxycytidine and Histone Deacetylase Inhibitor Depsipeptide on Human Breast Carcinoma Cells," <i>Int. J. Cancer</i> , (2003) 103:177-184.			
EXAMINER SIGNATURE				DATE CONSIDERED	



Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application No.	09/841,744
				Filing Date	April 24, 2001
				First Named Inventor	Jorge F. DiMartino
				Art Unit	1653
				Examiner Name	Chih-Min Kam
Sheet	2	Of	2	Attorney Docket No.	12636-891
OTHER PRIOR ART – NON PATENT RELATED DOCUMENTS					
Examiner Initials*	Cite No.¹	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published			T²
		SANTINI, V., et al., "Changes in DNA Methylation in Neoplasia: Pathophysiology and Therapeutic Implications," <i>Annals of Internal Medicine</i> (2001) 134:573-586.			
		SCHRUMP, D.S., et al., "Phase 1 Study of Sequential Deoxyazacytidine/Depsipeptide Infusion in Patients With Malignancies Involving Lungs or Pleura," <i>Clinical Lung Cancer</i> , (2002) 186-192.			
		SHAKER, S., et al., "Preclinical Evaluation of Antineoplastic Activity of Inhibitors of DNA Methylation (5-aza-2'-deoxycytidine) and Histone Deacetylation (Trichostatin A, Depsipeptide) in Combination Against Myeloid Leukemic Cells," <i>Leukemia Research</i> 27, (2003) 437-444.			
		SMIRAGLIA, D.J., et al., "The Study of Aberrant Methylation in Cancer via Restriction Landmark Genomic Scanning," <i>Oncogene</i> , (2002) 21:5414-5426.			
		WAJED, S.A., et al., "DNA Methylation: An Alternative Pathway to Cancer," <i>Annals of Surgery</i> (2001), 234(1):10-20.			
		WEISER, T.S., "Sequential 5-Aza-2'-Deoxycytidine-Depsipeptide FR901228 Treatment Induces Apoptosis Preferentially in Cancer Cells And Facilitates Their Recognition by Cytolytic T Lymphocytes Specific for NY-ESO-1," <i>Journal of Immunotherapy</i> , (2001), 24(2):151-161.			
EXAMINER SIGNATURE				DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.